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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,272	08/13/2001	Christoph Kirsch	9730-001	3234
30448 7590 05/28/2008 AKERMAN SENTERFITT P.O. BOX 3188 WEST PALM BEACH, FL 33402-3188				
EXAMINER				
MARVICH, MARIA				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/831,272

Applicant(s)

KIRSCH ET AL.

Examiner

MARIA B. MARVICH

Art Unit

1633

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 42-49 is/are pending in the application.
- 4a) Of the above claim(s) 1, 4-7, 10-21, 23-38 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 8, 9, 22, 39, 42-47 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/3508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This office action is in response to an amendment filed 2/19/08. Claims 1-40 and 42-49 are pending in the instant application. Claims 1, 4-7, 10-21, 23-38 and 40 are withdrawn.

Election/Restrictions

This application contains claims 1, 4-7, 10-21, 23-38 and 40 are drawn to an invention nonelected with traverse in the reply filed on 5/3/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim 46 is directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claim 46, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, is hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 1/28/04 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re*

Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Therefore, claims 2, 3, 8, 9, 22, 39 and 42-49 are under examination.

Claim Objections

Claims 2, 3, 42 and 46-49 are objected to because of the following informalities: claims 2, 3, 42, 47, 48 and 49 for completeness should insert --the-- prior to --expression is induced by elicitor treatment, pathogen infection, or both --.

In claim 2 and 3 the claims use both "the" and "said" when referencing the previous limitations. Both are redundant and unnecessary. It would be remedial to delete either "the" or "said". As well, in claim 43, the recitation of "at least one of the said two or more cis-acting elements" is confused by its being 4 elements, 2 of SEQ ID NO:11 and 2 of SEQ ID NO:7. It would be clearer if the claims simply recited --wherein the two or more cis-acting elements comprise--.

Claims 2, 3 and 49 have spaces that need to be deleted between "specific" and "expression".

Claim 8 recites "spacer region composed of 4 to 10 base pairs separates at least two of said cis-acting elements" which for consistency and clarity should be amended to recite as in claim 9--said two or more cis-acting elements are separated by a spacer of between about 4 to 10 base pairs--.

Claim 39 recites "local gene expression which for accuracy should be --local gene expression in plants--. In line 5, the recitation "wherein the promoter comprises" would be

preferable if recites as --wherein the at least one cis-element is-- and similarly in line 7 as --and the at least one elements comprises--.

Claim 46 is drawn to a method for the production of transgenic plants, plant cells or plant tissue wherein the method comprises introduction of the chimeric promoter into the genome of a plant, plant cell or plant tissue. It appears applicants intend that the plant cells and plant tissue as well as the plants are transgenic. Rather, the claim appears to read on a method of producing a transgenic plant or a plant cell or a plant tissue. The claim language should be clarified. As well it would be proper to recite --comprises introducing the chimeric--.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van de Locht et al (EMBO J, 1990, vol 9(9) p 2945-2950; see entire document) in view of Pears and Williams (Nucleic Acids Research, 1988, Vol 16(17), pages 8467-84861; see entire document) and Searle et al, MCB, 1985, Vol 5(6), pages 1480-1489; see entire document) further in view of Comai et al (Plant Molecular Biology, 1990, Vol 15(3), pages 373-381; see entire document). **This rejection is maintained for reasons of record in the office action mailed 11/20/07.**

Applicants claim a chimeric promoter comprising two copies of SEQ ID NO: 11.

Van de Locht et al teach a promoter obtainable by insertion of pPR2-10, which comprises at least one cis-acting element sufficient to direct elicitor-specific expression into the promoter of the GUS reporter gene. pPR2-10 comprises SEQ ID NO:11 (nucleotides -77 to -46) as indicated in figure 5, which demonstrates that pPR2-10 comprises the region from -168 to -43. This region comprises SEQ ID NO: 11 and functions as a cis-element sufficient to direct elicitor specific expression with the CAAT element. The promoter of van de Locht et al as disclosed in Figure 5 and 6 is a chimeric promoter formed by fusion of parsley chalcone synthase promoter (which provides the minimal promoter) to a PR2 fragment. Van de Locht et al do not teach that pPR2-10 comprises two copies of the elicitor element.

Pears and Williams teach that promoter sequences inserted into promoters can mediate sufficient gene expression (see e.g. abstract). Specifically, Pears and Williams teach that the promoter elements function "optimally" when multiple copies of the sequences are present (see e.g. page 8480 and figure 7).

Searle et al teach that promoters comprising two heterologous inducible elements isolated from the methallothionein I gene function as strong inducible promoter, whereas a single element did not respond to zinc (see e.g. abstract). Applicants reason that more than two should further increase the inducibility of the promoter.

Comai et al teach that promoters can be duplicated with the effect of enhanced expression (see e.g. abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate the isolated promoter fragment that is elicitor responsive as taught by van

de Locht et al as taught by Pears and Williams and Searle et al and Comai et al because and van de Locht et al teach that a fragment of the PR2 promoter is responsible for strong elicitor mediated gene activation and because Pears and Williams and Searle et al teach that multiple elements are more effective than single elements and Comai et al teach that it is within the ordinary skill of the art to generate chimeric vectors in which larger promoter elements are duplicated. One would have been motivated to do so in order to receive the expected benefit of enhanced regulation of heterologous genes. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 103 on pages 18-22 of the amendment filed 2/19/08. Applicants' arguments filed 2/19/08 have been fully considered but they are not persuasive. Applicants argue that Van De Locht teaches away from the importance of SEQ ID NO:11 because its role in elicitor mediated expression is not recognized. Van De Locht isolates, clones and induces expression from a construct comprising SEQ ID NO:11. Hence, Van De Locht recognizes that a fragment comprising SEQ ID NO:11 is essential for the expression level demonstrated in figure 6. Given that instant claim 48 is drawn to a promoter *comprising* two copies of SEQ ID NO:11, there is no bar against having more than SEQ ID NO:11 in the inducible regulatory region. Hence, while Van De Locht does not further isolate sequences corresponding to SEQ ID NO:11 this does not teach away from using a fragment of DNA comprising it as the claims encompass such a construct. Furthermore, it is clear from Van De Locht's results that more than one element responsible for elicitor induced expression is

present in PR2. Specifically, looking at the loss of expression between PR12 and PR13 it is clear that deletion at -52 abrogates activation from this second element. The argument referred to from a Declaration by Dr Somssich filed 3/12/07 is that elicitor activity is missing using pPR2-11 and pPR-12 does not acknowledge that 3 fold induction occurs with both constructs, which is lost upon deletion at -52.

Applicants argue that the secondary references teach away from the instant invention. Applicants arguments' that increased activity was not demonstrated in Pears and William by way of induction of a heterologous promoter were considered and are persuasive. This has been deleted from the rejection. However, Pears and Williams do teach that multiple copies of regulatory sequences can be created and used for increased expression of downstream genes. Somssich argues in the Declaration filed 3/12/07 that Searle et al and Comai et al teach that duplication of promoter elements consistently leads to increased but one cannot use these findings to generalize these findings. and provide three references in which duplication of elements does not enhance expression. As an initial point, KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. What is required is a teaching in the art that the means and technologies to duplicate promoter sequences are well known in the art. In this case, all of Pears, Searle et al and Comai et al teach that it was well known in the art to do so. Specifically, the teachings of Pears and Williams, Searle et al and Comai et al teach that duplication of regulatory or promoter regions is of ordinary skill in the art. Furthermore, the references teach that it is of ordinary methodology to identify those promoters that once duplicated give desired results. Specifically, Searle et al teach that promoters comprising duplication of MREs were inducible and position to one another as

well as other elements had little effect (see figure 4). Comai et al teach, "There have been several reports on the effect of duplicating the 35S enhancer. In transgenic tobacco plants Kay et al. observed ten- fold enhancement in transcription by duplicating the -343 to -90 region, while Fang et al observed two-fold enhancement of transcription by duplicating the -209 to -46 region. Using transient CAT assays Odell et al. [23] did not observe any effect of duplicating the -392 to -55." While it is applicants' arguments that the failures argue against the successes, the art teaches that there is every reason to consider duplication of regulatory regions for enhanced expression. Furthermore, the claims do not espouse any desired phenotype of the construct. Rather, claim 48 is simply drawn to duplication of a regulatory region which in this case is SEQ ID NO:11. It would have been obvious to duplicate effective regulatory regions as identified in Van De Locht given that the art teaches that duplication can lead to enhanced activity.

Conclusion

Claim 48 is rejected.

Claims 2, 3, 42 and 46-49 are objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

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